

REMARKS/ARGUMENTS

Applicants respectfully request reconsideration and allowance of this application in view of the following comments.

Regarding the restriction requirement, the Examiner's comments about the species election being improper are not understood, and clarification is requested. The Examiner says the species elected are not claimed in claims 1, 3 and 11-14. However, the restriction requirement only called for an election of a disclosed species.

Claims 1, 3 and 14 were rejected under 35 USC § 102(b) as being anticipated by Whitbourne et al. ("Whitbourne"), US 6,110,483. In response, Applicants respectfully submit that Whitbourne does not constitute an anticipation of the rejected claims. There is in Whitbourne no specific disclosure of a combination as instantly claimed. Instead, the Examiner relies on isolated and unrelated portions of Whitbourne to support a finding of anticipation. However, such reliance on isolated and unrelated portions of Whitbourne is presumptively improper, and does not, as a matter of law, make out a *prima facie* case of anticipation.

It is well settled that "rejections under 35 U.S.C. 102 are proper only when the claimed subject matter is identically disclosed or described 'in the prior art.'" *In re Arkley et al.*, 172 USPQ 524, 526 (CCPA 1972). According to the Court:

"[F]or the instant rejection under 35 U.S.C. 102(e) to have been proper, the * * * reference must clearly and unequivocally disclose

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the claimed compound or direct those skilled in the art to the compound *without any need for picking, choosing, and combining various disclosures not directly related to each other* by the teachings of the cited reference. Such picking and choosing may be entirely proper in the making of a 103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 102, anticipation rejection.”

[Emphasis added.]

The Examiner here does exactly what *Arkley* directs cannot be done—he picks and chooses from various unrelated portions of Whitbourne to make a case of anticipation. This is improper.

According to the Examiner, Whitbourne teaches a liquid coating composition comprising hydrophobic stabilizing polymers, hydrophilic polymers, including PEG, bioactive agents, including gentamicin, and another polymer, including PVC. However, Whitbourne’s teachings are hopelessly broad. Whitbourne nowhere teaches a specific composition, or a subgenus containing all of these materials, or even relating all of these materials to one another. Under the *Arkley* logic, Whitbourne clearly does not constitute an anticipation of the instant claims.

Thus, for example, Whitbourne does mention polyethylene glycol (PEG) at column 5, line 17. However, PEG is described by Whitbourne as one of many suitable hydrophilic polymers in an exceedingly long list that spans column 5, lines 16-34. The list includes literally

thousands of specials of which PEG polymers are only a few. The Examiner has not pointed to anything in Whitbourne that would have motivated persons skilled in the art to select PEG as opposed to some other hydrophilic polymer.

Likewise, Whitbourne does mention gentamicin *free base* at column 9, lines 13-14. However, the rejected claims require a sparingly soluble antibiotic salt. Whitbourne does mention gentamicin salts at column 9, lines 18-20, but then teaches away from their use by commenting that they must be converted into organic salts in order to be useful in the solvents used in the invention. This coupled with the fact that Whitbourne specifies the use of the free base in his Example 18, which is the only example to include gentamicin, would actually have led persons skilled in the art away from the use of gentamicin salts. Moreover, there is no teaching or suggestion in Whitbourne that such salts are sparingly soluble gentamicin salts. Most importantly, there is nothing directly relating a selection of PEG, on the one hand, and a gentamicin salt, on the other hand, for inclusion in the same antibiotic polymer combination. Consequently, Whitbourne cannot anticipate the present claims.

In a similar vane, Whitbourne does teach PVC has a possible additional polymer at column 7, line 34, but clearly such use is optional and, moreover, unlikely, as Whitbourne also teaches at column 7, lines 37-40, that "[s]uch additional polymers are not necessary to achieving the advantages of the invention, in contrast to prior art coatings relying on some of these polymers." Whitbourne also teaches at column 7, lines 34-35, that the polyvinyl chloride (along with the numerous other classes of additional polymers mentioned) is preferably in an inner layer of the combination, which teaches against a homogeneous distribution as required by the instant claims. Thus, this embodiment is not necessary to Whitbourne's results, and, therefore, not

likely to be included, and, further, even if it were included, Whitbourne leads to a heterogeneous distribution of this material in contrast to the homogeneous distribution required by the instant claims.

Respectfully, Whitbourne lacks sufficient specificity to anticipate the present claims. The components of the present invention that the Examiner alleges can be found in Whitbourne are found among long lists and optional ingredients, and there is nothing in Whitbourne highlighting them or their combination in a way that would achieve the present invention. Under the patent law, this type of disclosure is inadequate to constitute an anticipation of the instant claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
NORRIS McLAUGHLIN & MARCUS, P.A.

By 

Kurt G. Briscoe
Attorney for Applicant(s)
Reg. No. 33,141
875 Third Avenue
18TH Floor
New York, New York 10022
Phone: (212) 808-0700
Fax: (212) 808-0844

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